



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5113 LEESBURG PIKE
FALLS CHURCH VA 22041

DASG-HCA

12 January 2006

MEMORANDUM FOR Commanders of Units or Activities Executing Force Health Protection Measures

SUBJECT: Agreement to Participate in Anthrax Vaccine Immunization Program (AVIP)

1. References:

a. Deputy Secretary of Defense, Memorandum, Subject: Resumption of the Anthrax Vaccine Immunization Program Under Emergency Use Authorization (EUA), 25 Apr 05.

b. Under Secretary of Defense (Personnel & Readiness), Memorandum, Subject: Implementation of Resumption of the Anthrax Vaccine Immunization Program Under Emergency Use Authorization (EUA), 29 Apr 05.

c. Assistant Secretary of Defense (Health Affairs), Memorandum, Subject: Continuation of the Anthrax Vaccine Immunization Program (AVIP), 22 Dec 05.

2. Initial and Ongoing Compliance. In accordance with references cited above and other documents, commanders of units or activities involved with anthrax immunizations will complete the compliance agreement (Attachment 1) and checklist (Attachment 2) before beginning these immunizations, and then report to the Military Vaccine (MILVAX) Agency monthly or as directed on their state of compliance (Attachment 3). The MILVAX Agency will acknowledge the compliance agreement and authorize immunizations to begin, subject to any local requirements. The report also may be submitted simultaneously to other elements in the unit's or activity's chain of command. The report shall include the following items.

a. Whether or not anyone was required to receive anthrax immunization against their will, or without being informed of the option to refuse, or otherwise in violation of the option to refuse.

b. In any case in which immunizations were given without an option to refuse, the report shall include a full explanation of the circumstances involved. Also describe the remedy(ies) to be implemented to prevent a recurrence.

3. Reporting.

a. The commander, deputy commander, officer-in-charge (OIC), or other knowledgeable officer with responsibility for immunization operations will approve the report as the “approving authority” (Attachment 3). [USAF: Clinic OIC prepares report; medical unit commander approves report. USMC: See instructions in governing MARADMIN message.] For ships or other isolated units where an independent-duty corpsman is the senior medical staff member, the corpsman may submit the approving authority-approved report. Within U.S. Central Command (CENTCOM), reporting channels may be modified to meet operational conditions; CENTCOM will issue specific instructions.

b. If a unit or activity fails to report, MILVAX Agency will contact the alternate points of contact listed on the compliance agreement. If necessary, the MILVAX Agency will contact the applicable Surgeon General’s Office. Vaccine supply requests will not be honored for units that do not report according to these procedures.

4. Timing. Submit reports (Attachment 3) by the fifth day of a month for activities of the previous month. For Jan 06, describe the interval from 15 Jan to 31 Jan 06. Submit subsequent reports for full calendar months (e.g., 1 to 28 Feb 06, due by 5 Mar). In your report, describe any involuntary immunizations identified during the interval of the report, even if the event occurred before that interval (back to 27 Oct 04). Report any involuntary immunizations to the MILVAX Agency as soon as recognized, without waiting for the next report cycle.

JOHN. D. GRABENSTEIN
COL, MS
Director

Attachment 1:
Anthrax Vaccine Immunization Program (AVIP) Compliance Agreement

Commanding Officer (CO)/Officer-in-Charge (OIC): read, sign, return to Director, Military Vaccine Agency, fax: 703-681-4692, DSN 761-4692. NIPR: vaccines@otsg.amedd.army.mil. SIPR: otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX). Voice: 703-681-5101, DSN 761-5101. Director will return an acknowledgment letter, authorizing receipt of anthrax vaccine shipments.

I read and understand the (fill in applicable date) ____ Jan 06 message from my Service headquarters, describing requirements for anthrax immunization. I recognize the 22 Dec 05 DoD policy against involuntary anthrax immunization.

Each of the items on the checklist (Attachment 2) has been fulfilled for our activity. I have included a copy of the **completed checklist** with this request. I understand the reporting requirements (Attachment 3). If the Military Vaccine (MILVAX) Agency does not receive a report on time, they may contact the people named below to obtain another copy.

For medical units: My staff has informed or reminded every healthcare worker with responsibilities for administering anthrax immunizations (including immunization back-up technicians) of the importance of confirming desire to receive anthrax vaccine before the actual injection. The final sequence involves ensuring the patient received an educational brochure and understands the right to refuse. Just before injection (once site and vaccine are prepared) ask the patient 'Do you want to receive the anthrax vaccine?' If the patient confirms, administer it. These steps are intended to prevent medication errors.

Our activity is ready to comply with the DoD policies for anthrax immunization. I accept responsibility for AVIP trifold distribution, education, and reporting.

If I am assigned other duties and am no longer responsible for this program, I will notify the MILVAX Agency before departure. I will instruct my replacement to complete his or her own Compliance Agreement and forward it to the MILVAX Agency.

(printed name, title)

(signature)

(date)

DSN telephone: _____ **E-mail address:** _____

This agreement corresponds to immunization team(s) for the following unit, ship, activity, or immunization clinic, specific name and address and zip code.

Unit/Activity/Ship/Clinic Name: _____

Address: _____ Zip code: _____ - _____

The medical activity storing anthrax vaccine and administering the anthrax immunizations, medical activity name and address and zip code (not required if same as above).

Unit/Activity/Ship/Clinic Name: _____

Address: _____ Zip code: _____ - _____

Alternate points of contact (Name, DSN telephone number, email)

	Name	DSN	Email
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____

Attachment 2:
Anthrax Vaccine Immunization Program (AVIP) Implementation Checklist

Date _____ Place where immunizations given _____

Installation/Ship _____ OIC / Commander _____

Ensure these items have been completed before giving anthrax immunizations:

- [] 1. Collect all previous AVIP trifold brochures from April 2005 or earlier and discard them. Do not retain them for future use. Be sure to remove obsolete trifolds from pamphlet racks in waiting rooms, on bulletin boards, intranets, etc.
- [] 2. Obtain sufficient AVIP trifolds dated 16 Dec 05 or later, enough to give a personal copy to each person to be vaccinated, one for each dose. Each anthrax vaccine shipment will include AVIP trifold brochures equal to the number of doses ordered. Additional color copies of these revised trifolds are available by emailing usammadoc@det.amedd.army.mil or at www.anthrax.mil/FDAOrder.
- [] 3. Obtain AVIP briefing slides. Available from www.anthrax.mil/FDAOrder. If you need these slides shipped to you in hard copy or on a CD-ROM, call 877-GET-VACC or send an email request to vaccines@otsg.amedd.army.mil, SIPRNET otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX).
- [] 4. Attachment 4 provides a prototype AVIP education roster. Use AVIP education rosters only confirm that each person to be offered anthrax immunization received an AVIP trifold brochure before each dose. This roster will be captioned "I received a trifold brochure for anthrax vaccine" or words to that effect. Rosters will include printed or typed name and date AVIP trifold received. Retain these rosters with unit records for 1 year. **Do not** collect signatures accepting/declining immunization on trifolds or any other document. Personnel **do not** sign that they accept or decline anthrax immunization, only that they received the AVIP trifold brochure.
- [] 5. Coordinate with supporting medical activity or ensure organic medical support has required AVIP training for vaccinators and healthcare providers. Assure all vaccinators (primary and back-up), clinical supervisors of vaccinators, preventive medicine and public health staff, and relevant healthcare providers (e.g., allergy-immunology, ambulatory care, flight medicine, emergency care) are familiar with the clinical science for anthrax vaccine and DoD requirements. Use training course available at www.anthrax.mil/education. Annotate training records accordingly. Vaccinators acknowledge the content in the following materials:
 - a. Service AVIP implementation message (available at www.anthrax.mil/FDAOrder).
 - b. AVIP healthcare provider briefing slides at www.anthrax.mil/education.
 - c. BioThrax package inserts: available with every vaccine vial or at www.bioport.com/AnthraxVaccine/Insert/AVAIInsert.asp.

- d. AVIP trifold brochure dated 16 Dec 05 or later.
 - e. Reporting procedures for Vaccine Adverse Events Reporting System (VAERS, www.vaers.hhs.gov).
 - f. Reasons for medical exemption from anthrax immunization (e.g., serious allergic reactions to anthrax immunization, moderate or severe illness, pregnancy, latex sensitivity, immune-suppressive conditions, Guillian-Barré syndrome, prior anthrax infection). The most effective way to identify early pregnancy is to ask discreetly for date of last menstrual period and whether the last menses was normal and on time. Offer pregnancy testing before any immunization.
- [] 6. Understand criteria for eligibility for anthrax immunization (Under Secretary of Defense (P&R) memo, 29 Apr 05; Service EUA-AVIP implementation messages, Army: 5 May 05. USCG: 12 May 05. USMC: 16 May 05. USAF: 20 May 05. Navy: 20 May 05. Available at www.anthrax.mil/EUA.
- [] 7. Understand the option to refuse, including both (a) the reasons why the military and civilian leadership of the Armed Forces strongly recommends immunization, as well as (b) the requirement that no one can be ordered or forced to be vaccinated under current DoD policy.
- [] 8. Inform or remind every healthcare worker with responsibilities for administering anthrax immunizations (including immunization back-up technicians) of the importance of confirming desire to receive anthrax vaccine before the actual injection. The final sequence involves ensuring the patient received an educational brochure and understands the right to refuse. Just before injection (once site and vaccine are prepared) ask the patient 'Do you want to receive the anthrax vaccine?' If the patient confirms, administer it. These steps are intended to prevent medication errors.
- [] 9. Assure unit/activity/command has sufficient trained personnel with passwords to enter data on the same day as immunization into immunization tracking system (e.g., MEDPROS, AFCITA, RAMIS/MRRS, SAMS, MRS, CHCS II). Or has a plan to train these people expeditiously, and can assuredly record immunizations on SF Form 601, DD Form 2766, Deployable Medical Record, PHS Form 731, or similar form.
- [] 10. Assure OIC or commander understands **reporting requirements** regarding option to refuse. These reports go to the Military Vaccine Agency, at the direction of the Deputy Secretary of Defense.
- [] 11. Assure OIC or commander understands need for officer(s) not directly involved in the AVIP to perform spot checks of anthrax immunization operations to assure the option to refuse can be freely exercised.

- [] 12. Assure logistics personnel have been trained in cold-chain management procedures, including prompt refrigeration of vaccines upon receipt. [Or freezing, in the case of *Varivax*, *ProQuad*, and *FluMist*]. Alarm systems are used to protect large inventories.
- [] 13. Assess available inventory of anthrax vaccine (e.g., in medical logistics warehouse). Arrange for shipment of initial quantity of anthrax vaccine, but clinics may not take physical possession of the vaccine until Military Vaccine Agency provides email approval of the Compliance Agreement.

Reassess items on this checklist periodically.

Attachment 3:
Anthrax Vaccine Immunization Program (AVIP) Report Template

MEMORANDUM FOR Director, Military Vaccine (MILVAX) Agency

Fax: 703-681-4692, DSN 761-4692. Voice 877-GET-VACC. DSN 761-5101

NIPR: vaccines@otsg.amedd.army.mil

SIPR: otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX)

SUBJECT: Report of Compliance with Conditions for Anthrax Vaccine Immunization Program (AVIP)

1. Report for the interval from <##> <Mon> 2006 through <##> <Mon> 2006:

[If the following sentence is true, submit it as your report. If the following sentence is not true, change the text to explain what occurred to make the proposed text untrue. Be sure to specify the number of people vaccinated without an option to refuse and be prepared to provide a list of their names.]

No one received anthrax immunization against his or her will, or without being informed of the option to refuse, or otherwise in violation of the option to refuse, at this unit.

2. Remedy. [If applicable, describe here steps taken to prevent noncompliance with DoD policy from happening again. If not applicable, state "not applicable."]

3. I certify the accuracy of this report to the best of my knowledge.

Name	Title	Date
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If faxed, sign on line above. If emailed, send as scanned PDF document or from approving authority's or alternate official's email account.

Zip code (eg, APO): _____ - _____

Contact email: _____

Contact telephone #: _____

Activity/Unit/Ship: _____

RUC/UIC: _____